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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/882,186	06/15/2001	Ish Kumar Khanna	3824/US	7998

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EXAMINER

HABTE, KAHSAI

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 02/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/882,186	Applicant(s) KHANNA ET AL.	
	Examiner Kahsay Habte, Ph. D.	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 30 January 2003.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 66-130 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 66-130 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	6) <input type="checkbox"/> Other: _____

DETAILED ACTION

1. Claims 66-130 are pending.

Response to Amendment

2. Applicant's amendment filed on 01/30/03 in response to the previous Office Action (Paper No. 10) is acknowledged. Rejections of claims 66-130 under 35 U.S.C. § 112, second paragraph (Paper No. 10, paragraphs 6a-6c) have been obviated.

Information Disclosure Statement

3. In regard to the IDS submitted on Paper No. 4 (Jan. 03, 2002), the examiner cannot locate the references. Applicants are kindly asked to furnish the references that are cited in the PTO 1449 (Paper No. 4).

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 66-130 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for B = carbocyclic ring, does not reasonably provide enablement for B = heterocyclic ring. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. There has been recited in

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claim 66 "X or Y are independently selected from the group consisting -CR9- or -N- ...the group X-X2-Y contains a moiety selected from the group consisting of acyl, alkyl, amino, ether, thioether.." but the specification is not enabled. Applicants are entitled to "phenyl" or other carbocyclic rings in ring B, but not to heterocyclic rings in B. According to the specification, many of the examples require B = phenyl ring. Applicants are invited to show any examples that requires heterocyclic ring in B to overcome the rejection. It is recommended that applicants limit their claim to what is actually made.

5. Claims 109-112 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. There has been recited the treatment of "tumor metastasis" in claims 109 and 110 and also the treatment of "solid tumor growth" in claims 111-112, but the specification is not enabled for the treatment of said tumors.

The claim sets forth the treatment of "tumor" generally. However, there never has been a compound capable of treating "tumor" generally. There are compounds that treat a range of cancers, but no one has ever been able to figure out how to get a compound to be effective against tumors generally, or even a majority of tumors. Thus, the existence of such a "silver bullet" is contrary to our present understanding in oncology. Even the most broadly effective antitumor agents are only effective against a small fraction of the vast number of different cancers known. This is true in part because tumors arise from a

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wide variety of sources, such as viruses (e.g. EBV, HHV-8, and HTLV-1), exposure to chemicals such as tobacco tars, genetic disorders, ionizing radiation, and a wide variety of failures of the body's cell growth regulatory mechanisms. Different types of cancers affect different organs and have different methods of growth and harm to the body, and different vulnerabilities. Thus, it is beyond the skill of oncologists today to get an agent to be effective against tumors generally, evidence that the level of skill in this art is low relative to the difficulty of such a task.

Further, "tumor" covers more than just cancers. It also covers many neoplasms, cancerous or not. A neoplasm is any abnormal tissue that grows by cellular proliferation more rapidly than normal, or continues to grow after the stimulus that initiated the new growth has ceased, or shows lack (partial or complete) of structural organization and/or coordination with surrounding tissue. It can be benign or malignant. Thus, such a term also covers precancerous conditions such as lumps, lesions, and polyps. In addition, "tumor" covers things other than neoplasms. It also covers any kind of swelling arising from inflammation. Thus, the claim would cover treatment of many kinds of inflammation. The specification cannot support that.

When the best efforts have failed to achieve a goal, it is reasonable for the PTO to require evidence that such a goal has been accomplished, *In re Ferens*, 163 USPQ 609. The failure of skilled scientists to achieve a goal is substantial evidence that achieving such a goal is beyond the skill of practitioners in that art, *Genentech vs Novo Nordisk*, 42 USPQ2nd 1001, 1006.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 66-130 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

a. In claim 66 (page 9, line 8), the phrase "B forms...ring system" is indefinite. What ring system? Is pyridine included? Diazines? What are covered and what are not? Applicants have to recite the monocyclic and bicyclic rings of "ring B" in order to overcome the rejection.

Response to arguments

Applicants' arguments filed 01/30/2003 have been fully considered but they are not persuasive.

Applicants argue by citing case laws (*Miles Lab. V. Shandon Inc.*, 27 USPQ2d 1123 (Fed. Cir. 1993) and *In re Robins*, 166 USPQ 552, 555 (CCPA 1970)) to show that the phrase "B forms...ring system" is definite. The examiner disagrees with applicants. Infringement issues of *Miles Lab. V. Shandon Inc.*, 27 USPQ2d 1123 (Fed. Cir. 1993) is

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different from the instant case. There is no mention in *Miles Lab. V. Shandon Inc.* or *In re Robins* that indicate rings can be defined the same way defined in the instant. The issue here is whether a ring is definite or indefinite. Applicants are silent in responding to simple questions raised above. According to page 10 of the specification, there is no guidance that can provide one skilled in the art to understand the type and the nature of the rings embraced. For example, on page 10 lines 1-2 it has been disclosed that "X-X2-Y optionally contains a moiety selected from the group consisting acyl, alkyl, amino, ether, thioether, sulfone and olefin", but it is unclear how these groups fit into the ring. If we take alkyl (R-) or acyl (R-CO-) that are monovalent groups, it is impossible to have said groups as a part of a ring. Alkyls and acyl groups can be a substituent on a ring, but not part of a ring. What about R-O-R (where R = alkyl) or R-S-R in a ring? For example, alkylene (e.g. -CH2-), -O-, -S-, -NH-, -SO2- are acceptable groups in a ring, since they are divalents.

The phrase "B..ring" remains unclear and indefinite. The public has to know, what type of rings are covered here and what are not? Applicants are recommended to recite all rings (bicyclic and monocyclic) that are covered by said phrase assuming they have enough support in the specification as was done for A¹ to overcome the rejection. Note that rings formed from B ring can be classified and searched if they come out ahead of the 546 classifications. For example, if applicants intend to claim diazines, additional search in class 544 is needed, if applicants intend to claim 7-membered ring with one or two nitrogens additional search in class 540 classes is needed.

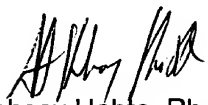
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Conclusion

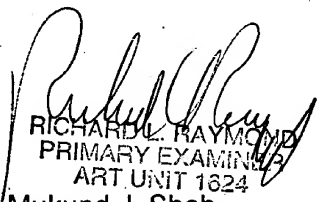
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kahsay Habte, Ph. D. whose telephone number is (703) 308-4717. The examiner can normally be reached on M-F (9.00AM- 5:30PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


Kahsay Habte, Ph. D.
Examiner
Art Unit 1624

KH
February 19, 2003


RICHARD L. RAYMOND
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